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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/887,977	07/03/97	WANG W	DX0589K1

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HM12/0709

EXAMINER	
KEMMERER, E	
ART UNIT	**PAPER NUMBER**
1646	15

DATE MAILED: 07/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/887,977	Wang et al.
Examiner	**Art Unit**
Elizabeth C. Kemmerer	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *2 Feb 1998*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4 and 23-45* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4 and 23-45* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The preliminary amendments files 23 October 1998 (Paper No. 13) and 02 February 1998 (Paper No. 14) have been entered in full.

Applicant's election of Group 11 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-3 and 5-22 are canceled. Claims 4 and 23-45 are directed to the elected invention and are under examination.

The Examiner, Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Elizabeth C. Kemmerer, Group Art Unit 1646.

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not accompanied by the required reference to the relevant sequence identifier (i.e., SEQ ID NO:). This happens at pp. 99, 101, for example.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: POLYNUCLEOTIDES ENCODING MAMMALIAN CHEMOKINE.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pp. 99 and 100, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The abstract of the disclosure is objected to because it consists of two paragraphs, and contains inappropriate information relating to the file history of the application. Correction is required. The second paragraph should be deleted. See MPEP § 608.01(b).

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 23-29, 42, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4 and 45 and its dependents, it is unclear what is meant by the "mature" portion of the polypeptide. Neither the specification nor the art unambiguously define the term. Is the mature portion the polypeptide minus a leader sequence, or properly folded and active, or glycosylated?

In claim 42, it is confusing that "at least 15 contiguous residues" is recited rather than "at least 15 contiguous **amino acid** residues". Since the other claims reciting polypeptide fragments specifically recite amino acid residues, it appears that something different is intended in this claim due to the slight difference in terminology. Neither the specification nor the relevant art would suggest what that is, however.

In claim 44, it is not clear what is meant by "selectively hybridizes" and "stringent hybridization conditions". Neither the specification nor the art unambiguously define the terms. Thus, the metes and bounds of the claimed invention cannot be determined.

35 U.S.C. §§ 101 and 112, First Paragraph, Enablement

Claims 4 and 23-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The claims are directed to isolated polynucleotides encoding SEQ ID NO: 10, fragments and variants thereof, vectors and host cells comprising same, methods of expressing the encoded polypeptides, and methods of producing a detectable nucleic acid duplexes therewith. No well-established utility exists for newly isolated biological molecules. The specification discloses the polypeptide of SEQ ID NO: 10 as well as polynucleotides encoding same, preferably SEQ ID NO: 9. See table 4. The specification asserts that the polypeptide of SEQ ID NO: 10 is a dendritic cell chemokine receptor (DC CR), based upon its source and structural similarity to other chemokine receptors. However, the specification does not disclose the ligand that specifically activates DC CR, nor what signal is transduced, nor what downstream physiological effect results from ligand binding. The relevant art teaches that chemokine receptor binding and response to specific chemokines are highly variable (see Murdoch et al., 2000, Blood 95:3032-3043; especially Abstract and Table 1). Therefore, the assertion that polynucleotides encoding SEQ ID NO: 10 have patentable utility in that they encode a chemokine receptor is credible and specific, but it is not a substantial asserted utility. Significant further research would be required to determine the receptor's ligand as well as the response to ligand binding, as evidenced by the art.

The specification also asserts other utilities of the claimed invention as follows:

1) to make antibodies which may be used therapeutically to block retroviral infection (p. 65): This asserted utility is credible and specific, but it is not substantial. The specification does not disclose any particular retroviruses which infect cells mediated through the DC CR. The identification of such would require substantial further research. Since this asserted utility is not presented in a readily available, mature form, it does not constitute a patentably utility.

2) plays a role in attracting appropriate cells for the initiation of an immune response, or plays a role in pulmonary physiology (p. 73): This asserted utility is also credible and specific, but not substantial. Since the ligand for the DC CR is not disclosed, the skilled artisan would be unable to activate the receptor in these roles. Also, it is not clear which cells would be recruited in the immune response, or what the pulmonary physiology role is. The determination of such would require substantial further research. Since this asserted utility is not presented in a readily available, mature form, it does not constitute a patentably utility.

Claims 4 and 23-45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 112, First Paragraph, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 23-35 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following claim limitations do not have adequate written description in the specificaiton as originally filed and constitute new matter:

- In claim 4 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 15 contiguous amino acid residues" of SEQ ID NO: 10, or for "a mature portion of SEQ ID NO: 10";

- In claim 23 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 19 contiguous amino acid residues" of SEQ ID NO: 10, or for "a mature portion of SEQ ID NO: 10";

- in claim 26 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "stringent wash conditions of 55°C and less than 400 mM salt";

- in claim 27 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 25 contiguous amino acid residues or SEQ ID NO: 10";

- in claim 30 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "stringent wash conditions of 55°C and less than 400 mM salt";

- in claim 31 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "wash conditions of 65°C and less than 300 mM salt";

- in claim 32 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 50 contiguous nucleotides of SEQ ID NO: 9" or "at least two non-overlapping segments of at least 15 contiguous nucleotides of SEQ ID NO: 9";

- in claim 35 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for any of the recited segments of SEQ ID NO: 10 or a plurality of same;

- in claim 40 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for a "conservative substitution";

- in claim 41 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "an extracellular segment";

- in claim 42 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 15 contiguous residues of SEQ ID NO: 10";

- in claim 43 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 25 contiguous amino acid residues of SEQ ID NO: 10";

- in claim 44 and its dependent claims, the specification as originally filed does not appear to provide adequate written description for "at least 22 contiguous nucleotides of the complement of the polynucleotide of claim 36"; and

- in claim 45, the specification as originally filed does not appear to provide adequate written description for "a mature polypeptide".

Conclusion

No claims are allowed.

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Zaballos et al., October 1996, Biochem. Biophys. Res. Commun. 227:846-853. This reference discloses a coned chemokine receptor which is 98.4% identical to SEQ ID NO: 9 (nucleotide level) and 88.2% identical to SEQ ID NO: 10 (the amino acid level). However, the reference was released to the public in October of 1996, three months after the earliest provisional application's filing date of the instant application. Provisional application 60/021,664 discloses the exact sequences set forth in SEQ ID NO: 9 and 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
June 15, 2001

08/ 887977

Attachment 15

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.